Pharmacist Vaccine Administration: Practice Guide

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Immunisation Section

Communicable Disease Control Branch

Government of South Australia

SA Health

Document History

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Introduction

Background

Immunisation programs in Australia have been vitally important in eradicating or minimising vaccine preventable disease in the community for the benefit of all Australians.

Community confidence in immunisation programs remains vital to ongoing success. To strengthen and support immunisation services and programs, priority should be given to;

- Maintaining or improving high immunisation coverage rates,
- Effective governance of immunisation programs
- Establishing and maintaining an adequately skilled immunisation workforce
- Enhanced vaccine safety surveillance
- Public support and program confidence.

Good governance has been identified by the World Health Organization as the primary principle of the Global Vaccine Action Plan (WHO 2024), and governance has further been identified as a proposed priority in the Australian National Immunisation Strategy 2025 to 2030. With the fast pace of new vaccine developments and public health priorities, strong governance ensures effective programs, high coverage rates, and public confidence.

Over the past decade, pharmacists have played a vital role in increasing public health and safety through the delivery of some immunisation services. By establishing clear standards and guidelines, pharmacists can ensure consistency, quality control, and adherence to best practice in program management and clinical activities related to immunisation. This helps to maintain public trust, improve overall outcomes, and enhance effectiveness in promoting population health through immunisation.

Resources

Resources for pharmacists undertaking vaccination services;

- Australian Immunisation Handbook (as referenced in regulation 18(3a) of the *Controlled Substances (Poisons) Regulations 2011*)
- National Immunisation Program Vaccinations in Pharmacy (NIPVIP) Program
- Australian Department of Health and Aged Care: Australian Immunisation Register webpage
- Pharmaceutical Society of Australia: Practice Guidelines for pharmacists providing immunisation services.
- National Vaccine Storage Guideline ‘Strive for 5’
- PRASA Regulatory framework for the operation of pharmacy premises
- National Centre for Immunisation Research and Surveillance Australia

Pharmacists working within scope of practice

This document does not seek to comprehensively describe professional requirements for pharmacists to be able to administer vaccinations and it is incumbent upon the individual practitioner to ensure they are working within their scope of practice and have all the requisite professional skills, relevant training, competencies and knowledge. This includes consideration of the existing national and state immunisation policy structures and legislation and assessment of the requirements specific to the individual patient and vaccine. Clinical governance framework, including appropriate risk assessments and quality management systems should be in place to ensure professional conduct, compliance with professional standards and patient safety.

It is the responsibility of individual pharmacists to ensure professional indemnity insurance includes coverage for all professional activities they undertake as part of their practice, including the administration of vaccines both with and without a lawful prescription (should they choose to offer both services).

Since 2013, the Pharmacy Board of Australia has recognised that the administration of vaccines as within suitably trained pharmacists' scope of practice.

Purpose and scope

The Pharmacist Vaccine Administration: Practice Guide document is a guiding document for pharmacist vaccination service providers to:

1. Provide practical guidance to assist organisations and pharmacists delivering a vaccination service to meet their legislative and professional responsibilities; and
2. Support pharmacists in meeting community expectations for a safe and high-quality vaccination service incorporating best practice and quality standards.

Regulation

From February 2015 until January 2025, the Vaccine Administration Code (the Code) provided the legal authority under the South Australian Controlled Substances legislation for pharmacists to administer schedule 4 vaccines without a lawful prescription.

From January 2025, regulation 18(3a) of the *Controlled Substances (Poisons) Regulations 2011*, allows for a pharmacist who has successfully completed specified immunisation education and training requirements to administer a schedule 4 vaccine in accordance with the Australian Immunisation Handbook (or another approved resource if information on the vaccine is not yet available in the Australian Immunisation Handbook).

Pharmacists who provide vaccination services must ensure they are always working within their individual professional scope of practice, they have the requisite knowledge and are adequately skilled to provide the vaccination services they offer.

Clinical governance

Delivery of a vaccination service is complex and requires effective clinical governance to ensure program effectiveness, public safety and effective management of vaccine stock. To achieve clinical effectiveness and safety, multiple integrated components must operate effectively together.

These include;

- legislative frameworks and structures,
- policies, protocols and clinical guidelines,
- effective collaboration with all stakeholders,
- a trained and effective workforce,
- educational and training opportunities,
- effective management of vaccine stock and cold chain requirements, and
- availability and use of appropriate facilities, equipment, information, and resources to support vaccination service planning, delivery, and post care processes.

SA Health has systems in place for the delivery of well-managed, high quality, government-funded immunisation programs that are evidence-based and responsive to the needs of the South Australian community.

Pharmacist employers and individual pharmacists providing vaccination services (including the administration of privately funded vaccines) must have clinical governance systems and policies in place for the safe and high-quality delivery of vaccination services.

Employers should have in place a framework for determining a health practitioner's scope of clinical practice, and managing issues that may arise in maintaining an agreed scope of practice. It is recommended that organisations employing pharmacist immunisers should obtain and periodically review evidence that the practitioner has attained the appropriate credentials required for their individual scope of practice as a pharmacist immuniser.

Pharmacists must have successfully completed the minimum education and training as specified under regulation 18 (3a) of the *Controlled Substances (Poisons) Regulation 2011*. In addition, pharmacists must have completed appropriate education and training to support their personal scope of practice (refer "Training Requirements" below). This includes understanding the parameters for immunisation program administration, such as cohort eligibility under specified government-funded immunisation programs or clinical appropriateness of any private vaccines administered.

Government funded vaccine programs

The Commonwealth Government, NIPVIP Program eligibility defines the premises where vaccines can be administered, cohorts eligible to receive funded vaccines, and the provision of NIPVIP Program immunisation services in accordance with the following:

- Applicable state or territory requirements/legislation
- Australian Technical Advisory Group on Immunisation (ATAGI) Guidelines
- Australian Immunisation Handbook recommendations
- The National Immunisation Program (NIP)- South Australian Schedule, and
- PSA Practice Guidelines for the provision of immunisation services

Pharmacists (along with all other practitioners administering NIP vaccines) must not administer NIP government-funded vaccines for reasons outside of a specified program or the NIP- South Australian Schedule.

Each community pharmacy site participating in the NIPVIP Program must be registered with the SA Health Vaccine Distribution Centre (VDC) https://vdc.sa.gov.au/. The VDC supplies vaccines to organisations delivering government funded programs.

There are several other immunisation programs which are government funded, but not a part of the NIP. These may be funded by the state government or other unique funding mechanisms and may be a part of outbreak response or other public health programs. Examples of funded vaccines that are not part of the NIPVIP program include the Japanese Encephalitis Virus (JEV) vaccine, Meningococcal B (Bexsero®) and COVID-19 vaccine. The SA Health website will contain the most up-to-date information non-NIP funded programs.

Privately funded vaccines

Pharmacists may administer privately funded vaccines in accordance with their individual scope of practice. Pharmacists and employing organisations are responsible for the ordering, management and storage of vaccine stock required for privately funded vaccine services.

Vaccines administered for the purpose of travel

From January 2025, regulation 18(3a) of the *Controlled Substances (Poisons) Regulations 2011* allows pharmacists to provide private vaccinations, including for the purposes of travel. Importantly, for pharmacists to provide travel vaccination services they must have the relevant knowledge and skills for travel vaccination to be a part of their individual scope of practice. This includes specific travel healthcare training, relevant to the vaccinations which are being offered by the pharmacist.

Travel vaccination is only one part of travel medicine, and pharmacists may need to refer patients to a GP or travel medicine practitioner if the services required are beyond the scope of practice of the pharmacist.

Training requirements

A pharmacist undertaking vaccination service delivery must have undertaken a level of training that reflects the domains and learning objectives of the *National Immunisation Education Framework for Health Professionals*.

In accordance with regulation 18(3a)(a) of the *Controlled Substance (Poisons) Regulations 2011*, minimum training undertaken must be accredited by the Australian Pharmacy Council (APC), Health Education Services Australia (HESA) or 18(3a)(a)(iii) may be utilised to approve another accrediting organisation. It is pertinent that pharmacists ensure whichever education and training program they choose to undertake meets the South Australian legislative requirements. Pharmacy degree programs which have been accredited through the APC are listed on their website. The Australasian College of Pharmacy is approved under 18(3a)(a)(iii).

Ongoing competency in the delivery of various immunisation services can be demonstrated through assessment of practice and participation in continuing education programs that align to scope of practice. Ongoing registration with the Australian Health Practitioner Regulation Agency (AHPRA) requires pharmacists to maintain currency of skills and knowledge through development of a personal continuing education plan, completion of continuing education activities, and evidence of relevant professional practice.

Pharmacists delivering vaccination services must ensure their provider First Aid training is current (updated every 3 years) and they must complete annual Cardiopulmonary resuscitation (CPR) training.

In addition to education and training on the basic principles of administering vaccines, pharmacists must be trained in specific areas of practice relevant to their scope of vaccine administration. For example, if providing vaccines for the purpose of travel, the pharmacist must have successfully completed appropriate education and training to reflect this area of practice. Certain vaccines may require additional specialised training.

Pharmacist immunisers are expected to comply with the PSA Practice Guidelines for the provisions of immunisation services and PSA Professional Practice Standards. A self-assessment tool accompanies this Practice Guideline and is recommended to assist pharmacists and organisations assess and improve their vaccination services.

Premises and immunisation service provision

Pharmacists can provide immunisation services in any practice setting when working in the ordinary course of their profession, this may include a community pharmacy setting, through outreach or mobile immunisation programs. Community pharmacies providing vaccination services must be registered by

the Pharmacy Regulation Authority of South Australia (PRASA) under the *Health Practitioner Regulation National Law (South Australia) Act 2010* and their vaccine administration area must meet the requirements of the PRASA regulatory framework for the operation of pharmacy premises.

Pharmacists who provide services, including vaccination services, to children should have valid and periodically updated working with children checks in accordance with their obligations under the *Child Safety (Prohibited Persons) Act 2016 (SA)* and *Child Safety (Prohibited Persons) Regulations 2019 (SA).*

Pharmacists may conduct off-site vaccinations (i.e. outside their usual place of practice) if both the pharmacy and the off-site vaccination location are in a state or territory that has regulatory arrangements allowing pharmacists to vaccinate outside of the pharmacy premises. Pharmacists must ensure they are aware of and adhere to the relevant requirements of the state or territory in which they are practising. It is the pharmacists responsibility to ensure all requirements are met.

Pharmacists should ensure they have read and follow the National Vaccine Storage Guidelines 'Strive for 5' for packing and monitoring of vaccine stock while working outside of a pharmacy setting.

All equipment used for storage and transportation of vaccines should comply with the recommendations outlined in 'Strive for 5' and the Australian Immunisation Handbook, and should include:

- a purpose-built vaccine refrigerator with a temperature data logger
- coolers, data loggers, min/max thermometers, cooler ice packs and insulation materials for mobile or outreach immunisation clinics
- all necessary consumables required for vaccine administration
- an anaphylaxis response kit (ensuring supplies are in-date and a process exists to regularly check the quality and expiry of stock)
- an appropriately sized sharps container to dispose of clinical waste, including used syringes and needles.

Resources that are required to be readily accessible include:

- the online Australian Immunisation Handbook
- the current edition of the National Vaccine Storage Guidelines – Strive for 5
- materials to support communication about immunisation (e.g. patient handouts or leaflets) including information on the management of Adverse Events Following Immunisation (AEFI)
- the PSA Practice Guidelines for the provision of immunisation services.

Quality Care Pharmacy Program (QCPP) is a quality assurance program for community pharmacies. QCPP provides support and guidance on professional health services and pharmacy business operations. It is a requirement that pharmacies ordering government funded vaccines from the SA Health Vaccine Distribution Centre are QCPP accredited for Vaccination Services in the Pharmacy.

Provisionally registered pharmacists (intern pharmacists) may administer vaccines under the direct supervision of a registered pharmacist. Both the supervising pharmacist and the provisionally registered pharmacist need to meet all the legislative requirements outlined in regulation 18(3a). The regulation specifically facilitates registered pharmacist administering vaccines, therefore students cannot administer vaccines under regulation 18(3a).

Recording and reporting

Organisations should collect and retain records in accordance with organisational policies and legislative requirements. Requirements to maintain consumer privacy and confidentiality must be considered. It is good practice to provide a record of the vaccine(s) administered to the consumer, details on when further doses are due (if applicable) and what to expect following vaccine administration, including how to manage and report an AEFI.

Pharmacists should be aware of both their mandatory and best practice Australian Immunisation Register (AIR) recording obligations under the *Australian Immunisation Register Act.* The AIR also acts as a resource for facilitating transfer of clinical information, so timely and accurate completion is essential to ensure all health practitioners are aware of individual consumer's vaccination history. Further details are outlined under Protocols, 5 *Record keeping and recording* of this document.

Vaccine funding and payment arrangements

Community pharmacies that choose to register as a NIPVIP Program immunisation provider will be funded to administer NIP vaccines to eligible people 5 years of age and older.

NIP vaccines must be administered with no out-of-pocket costs to the consumer and no additional service fee may be charged to the consumer.

More information about the NIPVIP Program is available from the Pharmacy Programs Administrator webpage.

For consumers eligible for other non-NIP funded vaccines, pharmacies can charge a service fee for administration of the vaccine, with the exception of the state-funded Japanese encephalitis vaccines. Consumers must be made aware of the potential availability of state-funded vaccines and free vaccination services through bulk-billing general practitioners or local council or community immunisation clinics, prior to administering the vaccine.

For private vaccines (those not funded under the NIP or other government funding mechanisms), the pharmacy may charge for the cost of the vaccine plus an administration fee as determined by the individual pharmacy business.

All relevant charges should be understood by the consumer receiving the vaccine or the person responsible for the payment (parent/guardian), prior to the commencement of any pre-screening activity and/or the administration of any vaccine.

Practice guides

1. Cold chain

Cold chain and vaccine management processes must be effective to ensure the availability of safe and viable vaccines through pharmacist vaccination services.

The National Vaccine Storage Guidelines, 'Strive for 5' contain specific details for setting up the infrastructure for a vaccination service and must be incorporated within the organisational policies. To comply with national cold chain requirements, pharmacists are required to complete a vaccine storage self-audit every 12 months.

Compliance with 'Strive for 5' includes, but is not limited to:

- annual 'vaccine storage self-audit' as per the current ‘Strive for 5’ and correction of any issues identified
- effective staff knowledge and regular training on ‘Strive for 5’ and the additional information on vaccine storage, cold chain breach management and back up plans on the SA Health Vaccine Ordering and Storage webpage;
- use of a purpose-built vaccine fridge with a data logger;
- accurate and effective fridge temperature monitoring processes, including the ability to download, record and save data logger information;
- prompt identification and reporting of any cold chain breach outside of +2° to +8 °C with affected vaccines being isolated and not used until appropriate advice has been sought;
- effective cold chain back-up plan in case of power or fridge failure;
- appropriate vaccine ordering processes that ensure adequate stock is available without stockpiling or overcrowding the fridge;
- storage and transport of vaccines in their original packaging; and
- effective and compliant Cold Chain management when required outside of the pharmacy premises, as described in detail in ‘Strive for 5’.

2. Identifying and reporting a cold chain breach

For NIP or other state-funded vaccines, **SA Health must be notified by contacting the Immunisation Section on 1300 232 272** during business hours (Monday- Friday 9:00am-5:00pm), so advice can be provided on the viability of vaccine/s as per stability data, and if they are able to be used. If a cold chain breach is identified outside of business hours of the Immunisation Section, any affected vaccine stock should be quarantined in a compliant, working vaccine fridge until advice can be sought. See the SA Health website for details at Vaccine storage.

In the event of a cold chain breach related to private vaccine stock, the pharmacist or delegated pharmacy staff should follow their organisation’s cold chain breach policy which may include contacting the manufacturer for advice.

3. Pre-screening and consent

Vaccine providers must undertake pre-screening of consumers wishing to be vaccinated to identify contraindications or precautions, obtain valid consent, and ensure they are able to provide the vaccine services the individual consumer requires.

In South Australia, the *Consent to Medical Treatment and Palliative Care Act 1995* must be adhered too. Under this legislation, persons aged 16 and over with decision making capacity, have the right to consent or refuse to consent to their own medical treatment and/or healthcare.

The Australian Immunisation Handbook’s Preparing for vaccination chapter outlines the steps for pre-screening and obtaining consent, including consent on behalf of a child, adolescent, or adult lacking capacity.

4. After vaccination

The Australian Immunisation Handbook’s After vaccination chapter provides guidance on immediate after care, management of adverse events, and documenting immunisation.

Pharmacists must advise the person or the person and their parent and/or guardian to remain on the premises at which they were vaccinated for a minimum of 15 minutes post-vaccination, to allow for

immediate attention in the event of an adverse event following immunisation. Seating must be offered near the immunisation area and within the line of sight of the pharmacist or a person qualified in first aid and cardiopulmonary resuscitation.

5. Record keeping and reporting

It is best practice to record *all* vaccines administered in the Australian Immunisation Register (AIR). This ensures that individuals have a complete record of their vaccinations.

Under the *Australian Immunisation Register Act 2015* (Cth), all COVID-19, influenza, NIP, and Japanese encephalitis virus (JEV) vaccines administered must be reported to the AIR. A civil penalty may apply under the *Australian Immunisation Register Act 2015* if an organisation fails to complete mandatory reporting of vaccine administration to the AIR within designated timeframes.

Pharmacists and organisations employing pharmacists can register with the AIR by completing the 'Australian Immunisation Register - Application to register as a vaccination provider form'.

More information on the AIR reporting requirements is available on the Australian Government Department of Health and Aged Care webpage, Using the Australian Immunisation Register.

6. Adverse events and reporting requirements

An Adverse Event Following Immunisation (AEFI) is an unwanted or unexpected event following the administration of a vaccine(s). AEFIs may be caused by a vaccine(s) or may occur by coincidence (that is, the event would have occurred regardless of vaccine administration).

Prior to administration of any vaccine, the consumer (or their parent and/or guardian) should be informed about the potential side effects of the vaccine, how to manage them, and who to notify of delayed adverse events that may occur once they have left the premises where they were vaccinated.

It is best practice for the consumer or parent/guardian to receive an after-vaccination leaflet explaining what vaccines have been administered, the common and uncommon side events and how to report an AEFI if necessary. An example of an SA Health developed After Vaccination information leaflet can be found here.

Information on adverse events and reporting guidelines are available through the SA Health website.

Ensure that any known Notifiable Adverse Event Following Immunisation (notifiable AEFI) within the meaning of the *South Australian Public Health (Notifiable and Controlled Notifiable Conditions) Regulations 2025* is reported to SA Health.

7. Other safety requirements

When pharmacists are undertaking vaccine administration activities, including pre-screening and vaccine administration, they must not engage in any other activity simultaneously (including dispensing).

All vaccination service staff (including clinical and non-clinical staff) should be familiar with the vaccination service that is being provided, and be informed about their roles and responsibilities, particularly in relation to managing an AEFI.

Pharmacists undertaking a mobile or outreach vaccination clinic as a solo practitioner need to comply with all protocols and procedures set by the organisation that employs or otherwise engages them.

8. Complaints

Organisations or pharmacists should develop a process for complaints regarding vaccination services. At a minimum, all individuals who receive vaccination services should be advised that:

- Complaints relating to the pharmacist's professional practice should be directed to the Australian Health Practitioner Regulation Agency (AHPRA) by phoning 1300 419 495 or visiting the AHPRA website www.ahpra.gov.au.
- Complaints relating to the pharmacy premises should be directed to the South Australian Pharmacy Regulation Authority (PRASA) https://www.pharmacyauthority.sa.gov.au/
- Individuals may also bring a complaint against a health service provider to the Health and Community Complaints Commissioner (HCSCC) https://www.hcscc.sa.gov.au/

9. Emergency response protocol

Guidance on the management of anaphylaxis is available in the Australian Immunisation Handbook.

Pharmacists must have access to an in-date anaphylaxis response kit that complies with the recommendations in the current version of the Australian Immunisation Handbook available at: The Australian Immunisation handbook preparing an anaphylaxis response kit.

Administration of adrenaline is, at all times, undertaken in accordance with the procedures specified in the current edition of the Australian Immunisation Handbook; recognition and treatment of anaphylaxis https://immunisationhandbook.health.gov.au/resources/tables/table-recognition-and-treatment-of-anaphylaxis.

An emergency response protocol must be kept as part of the anaphylaxis response kit.

Acknowledgements

SA Health acknowledges the use of Victorian Pharmacist-Administered Vaccination Program Guidelines as authorised and published by the Victorian Government, 1 Treasury Place, Melbourne. State of Victoria, Department of Health, 3 October 2024 in the development of this protocol.

Available at Victorian Pharmacist-Administered Vaccination Program Guidelines https://www.health.vic.gov.au/immunisation/victorian-pharmacist-administered-vaccination-program-guidelines.

Definitions

Immunisation programs: immunisations delivered as part of programs designed to achieve high community coverage rates or protection of specific community cohorts.

NIPVIP: National Immunisation Program Vaccination In Pharmacy.

Non-NIP funded vaccines: vaccines funded by the government (state or commonwealth) which are not part of the National Immunisation Program.

Pharmacist immuniser: a registered Pharmacist who provides vaccination services.

***SA Schedule- National Immunisation Program*:** The annual schedule of routine vaccines supported under the NIP and South Australian state funded programs.

Vaccination services: services provided by health professionals associated with the advice, pre-screening, administration and aftercare of consumers being vaccinated.

For more information

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Telephone: 1300 232 272
www.sahealth.sa.gov.au

www.ausgoal.gov.au/creative-commons

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